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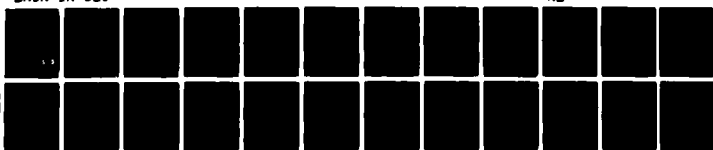
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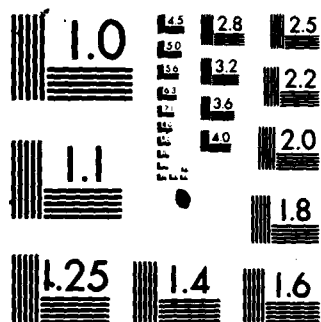
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PRIMARY DERMAL IRRITATION POTENTIAL OF COMPONENTS
OF THE M-258A-1 DECONTAMINATION KIT

WARREN W. JEDERBERG, CPT MS
JOHN T. FRUIN, DVM, PhD, COL VC
and
MARTHA A. HANES, DVM, CPT VC

TOXICOLOGY GROUP,
DIVISION OF RESEARCH SUPPORT

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**Primary Dermal Irritation Potential of Components of the M-258A-1
Decontamination Kit--Jederberg, Fruin and Hanes
Toxicology Series 31**

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Both aged and freshly made solutions gave the same results. The irritation caused by the solutions simulating field use, could be alleviated by rinsing the application site with physiologic saline. No assessment was made of the effects on the neutralizing capacity of the solutions by rinsing with saline.

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ABSTRACT

The chemical solutions (Decon I and Decon II) used in the M-258A-1 Decontamination Kit were tested for primary dermal irritation potential by using a modified Draize Test on rabbits. The raw solutions were tested both from aged and freshly made kits. The solutions were also tested at concentrations and under conditions simulating expected field use. All studies were conducted in compliance with the Good Laboratory Practices Act. The undiluted solutions caused caustic burns on the animals. At concentrations expected in field use, the solutions were irritating under the classification system used. Both aged and freshly made solutions gave the same results. The irritation caused by the solutions simulating field use could be alleviated by rinsing the application site with physiologic saline. No assessment was made of the effects on the neutralizing capacity of the solutions by rinsing with saline.



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PREFACE

This report summarizes the results of eight studies on the primary dermal irritation potential of the M-258A-1 Decontamination Kit. These studies were conducted in compliance with The Food and Drug Administration Good Laboratory Practices Act. The original data may be found in Institute Report No. 101 and Technical Notes No. 81-18TN, 81-21TN, 81-22TN, 81-24TN, 81-25TN, 81-26TN, and 81-27TN. Signatures of the principal scientists involved in each study and a report of compliance appear in the documents containing the original data.

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Primary Dermal Irritation Potential of Components
of the M-258A-1 Decontamination Kit--Jederberg, Fruin and Hanes
Toxicology Series 31

The urgent requirement for defensive measures and decontamination procedures was dramatically demonstrated to allied powers in the European Theater during World War I by the mass casualties resulting from the use of blister agents. Losses to the allies were high because they lacked defensive capabilities. Probably more important they lacked sufficient offensive chemical warfare capabilities to deter the enemy from using chemical agents. The offensive use of chemical agents is a violation of treaties and creates negative world opinion; however, clandestine use of offensive antipersonnel agents against guerrilla and poorly equipped forces has been reported in the popular press in recent years (1,2). The unclassified documentation about antipersonnel chemical warfare agents since World War I has been difficult to obtain and information about the use of offensive chemical agents has also been suppressed. The major military powers possess chemical warfare capability and have not initiated chemical attacks for fear of similar retaliatory strikes. Current Eastern Bloc doctrine, although rarely if ever published or discussed publicly, is presumed to stress the use of munitions containing chemical agents integrated into conventional fire patterns (3). Thus there remains an urgent need for the United States and her allies to continue to pursue vigorously research and development efforts in the area of medical defense against chemical warfare agents.

The rapid removal of chemical agents from the skin is an essential element in protecting personnel from chemical agents. The M-13 Kit, a Fullers earth preparation, was developed before the M-258 Kit as a means of removing chemical material by absorption (4,5). In addition to the physical removal of chemical agents active chemical neutralization is desirable. The M-258 Decontamination Kit, which is currently in the Army system, combines both physical removal and active chemical neutralization. (Neutralization continues after protective gloves, mask and garments are in place.)

The original M-258 Decontamination Kit was type-classified in the mid 1970s. It consisted of a plastic carrying case containing two plastic scrapers, a plastic container of Decon I solution, a plastic container of Decon II solution with a glass ampoule of Chloramine B enclosed, and cotton gauze pads. The instructions contained on the plastic container directed the user to remove any suspected chemical agent with the plastic scrapers. The user was instructed to open the Decon I container with the point of a nail which has its head imbedded

in the plastic container lid. He was then instructed to saturate one of the cotton gauze pads and wipe exposed and contaminated area for one minute. The user was then instructed to break the glass ampoule inside the Decon II, shake well, open Decon II with the nail, saturate another cotton gauze pad and wipe the same area 2 to 3 minutes (4).

The difficulty soldiers had in using the kit correctly, the caustic and irritating action of the chemical components, the abrasive action of wiping a limited area with a gauze pad for 4 minutes, and the potential for abrasion by broken glass from the Decon II container, were serious shortcomings of the M-258 Kit (6). Nevertheless, the benefit/risk evaluation of the kit was favorable, but the need for continued research and development efforts was recognized (Letter from US Armament Research and Development command, DADAR-CLW-E, to US Army Training and Doctrine Command, ATCD-CF-S, Subject: Product Improvement Proposal for Decontamination Kit M-258, dated 17 November 1977). Modifications have been made. The kit is now much easier to use, the risk due to abrasion by broken glass is lessened, and abrasion from the materials used to wipe the exposed skin is decreased (Contract Report ARCSL-CF-79046 to US Army Armament Research and Development Command for Contract DASKII-78-C-0025, Subject: Feasibility of Personnel Decontamination Kit, dated December 1979). The modified kit M-258A-1 consists of the plastic containers with six flex pouches. Three of the flex pouches contain pads saturated with Decon I solution. The remaining three pouches each contain pads impregnated with Chloramine B and breakable glass vials of Decon II solution inside a nylon mesh bag designed to contain glass particles (7).

Chemical Data:

The chemical analysis of Decon I appears in Table 1 and of Decon II in Table 2. Information about physiologic saline is outlined following the tables.

TABLE 1 (8)

CHEMICAL ANALYSIS OF DECON I
(pH = 10.6 - 10.8)

Component	ETOH	H ₂ O	Phenol	NaOH	NH ₄ OH
%	72 \pm 2%	q.s.	10 \pm 0.5%	5.0 \pm 0.5%	0.2 \pm 0.05%
Name	ethanol	water	phenol	sodium hydroxide	ammonium hydroxide
Molecular Structure	C ₂ H ₆ O	H ₂ O	C ₆ H ₆ O	NaOH	NH ₄ OH
Molecular Weight	46.07	18.016	94.12	40.01	35.036

TABLE 2 (8)

CHEMICAL ANALYSIS OF DECON II
(pH = 6.1 - 6.6)

Component	*LIQUID PORTION			*SOLID PORTION
	ETOH	H ₂ O	ZnCl ₂	Chloramine B
%	45 \pm 2%	50 \pm 2.5%	5 \pm 0.5%	100%
Name	ethanol	water	zinc chloride	Chloramine B (N-Chlorobenzene-sulfamido-sodium)
Molecular Structure	C ₂ H ₆ O	H ₂ O	ZnCl ₂	C ₆ H ₅ Cl NNaO ₂ S
Molecular Weight	46.07	18.016	136.29	213.64

* Equal quantities of liquid and solid are mixed to form Decon II.

Chemical name: Physiologic saline

Molecular structure: H₂O and NaCl

Molecular weight: 18.016 and 39.34

pH: 5.0 ± 2

Physical state: clear liquid, colorless, and odorless

Formulation: 99.1% H₂O and 0.9% NaCl

Manufacturer: Travenol Laboratories, Deerfield, IL 60015

Manufacturer Lot No: 2C655S1

Objectives

To determine the primary dermal irritation potential of:

1. The components of the M-258A Decontamination Kit by the standard primary dermal irritation (Draize) test.
2. The components of the prototype M-258A-1 Decontamination Kit
 - a. By the standard primary dermal irritation test (9).
 - b. When applied as the kits would be used in the field (10,11).
 - c. When applied as the kits would be used in the field with the addition of a step to remove the component of the kit (12).
3. Freshly prepared components of the M-258A Decontamination Kit when applied in the quantities that would remain on the skin after field use (13,14).
4. The abrasive action of the procedure for skin decontamination in the field with the M-258 Decontamination Kit (15,16).

METHODS

The animal model used for all tests was the New Zealand White rabbit, of either sex, weighing from 3 to 5 kg. After release from quarantine, six young normal animals were randomly selected for each test. The animals' backs were closely clipped from just posterior to the scapula to just anterior to the pelvis. Four test sites were designated on each animal: anterior right as I, posterior right II, anterior left III, and posterior left IV. Areas I and IV were intact on all animals, and areas II and III were abraded by making two perpendicular scratches in the stratum corneum of the skin about 1 1/2

inches long by using an escarifier. The four application sites were about 10 cm apart. A standard latin square table was used to randomize the test sites and a control site. The standard primary dermal irritation test (17) originally described by Draize (18) calls for 0.5 ml of liquid or 0.5 g of solid or semi-solid material to be applied directly to the skin, or if solid or semi-solid, placed under a 1-square-inch gauze patch.

The standard test calls for test substance impregnated pads taped over the test sites. A clear plastic strip, approximately eight inches wide, held by elastic tape was placed around the animal to retard evaporation and to insure skin contact by the test substance. The test substance was in contact with the skin for 24 hours. At the end of the exposure period, the wrapping was removed, the skin was wiped if material adhered, and the areas were scored. Depending on the objective of the individual test, test compound volume, method of application and post application procedures were modified as follows:

Objective 1: Two animals were used to test component issued M-258 kits. The standard primary dermal irritation test procedure was used.

Objective 2a: The standard test procedures were used except that rather than applying liquid test substance on gauze, liquid impregnated pads from the prototype M-258A-1 decontamination kit were cut into roughly one-inch (2.5 cm) squares and applied to the backs of animals. Decon I squares weighed about 0.3 g each, Decon II squares weighed about 0.6 g each. For Decon I dosing, two squares were applied one on top of the other. For Decon II dosing, one square was applied. For Decon I plus Decon II, smaller squares (0.5 to 0.7 inches (1.25 to 1.75 cm) square) were used. One Decon II pad was sandwiched between two Decon I pads of similar size. Using these dosing procedures, we anticipated an effective dose level of 0.5 g test substance per site.

Objective 2b: The standard test procedures were used except that rather than applying liquid test substance on gauze, liquid impregnated pads from the prototype M-258A-1 Decontamination Kit were cut into approximately one inch squares and applied to the test animals. Decon I squares were used to wipe the test area on the backs of rabbits for 1 minute. Decon II squares were used similarly, except the wiping was for 2 minutes. For Decon I plus Decon II the test site was first wiped for 1 minute with Decon I and then for 2 minutes with Decon II as divided for the use of the test kit. Test sites were occluded for one set of test animals. For the other set of test animals the exposure sites were left uncovered. Elizabethan collars were placed around the animal's neck to eliminate the possibility of self-mutilation at the test site.

Objective 2c: Methods were used identical to those in Objective 2b; in addition, the two sets of test animals received a saline wash of the site after application of test compounds. This was done by

scrubbing the application site five times with each of three surgical pads soaked in saline. Exposure sites in one group of animals were occluded and the other group was not occluded.

Objective 3: The standard test procedures were used but rather than applying 0.5 ml of liquid test substance, the amount was reduced to the amount needed to wet one square inch of close clipped rabbit skin (i.e. 0.04 ml per test site). Exposure sites on one group of animals were occluded; the other group sites were left to air dry.

Objective 4: The standard test procedures were used except that the test sites were not exposed to M-258 Kit chemicals but to the abrasive action of the application procedure. The dermal test sites were exposed by applying the test substances on gauze. The skin was then wiped for 1, 3 and 4 minutes with saline impregnated gauze. Exposure sites on one group of animals were occluded and on the other group they were not. Animals were scored at 24 and 72 hr and 14 days after exposure for edema/erythema (Table 3)

TABLE 3 (19)
EVALUATION OF SKIN REACTIONS

Erythema and Eschar Formation

No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate-to-severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injurious in depth)	4
Possible total erythema score	4*

Edema Formation

No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (edges raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4
Possible total edema score	4*
Possible total score for primary irritation	8

*Any skin reaction more serious than severe edema, vesiculation, ulceration, or necrosis places the chemical in Category IV.

Scores were tabulated for intact and abraded sites separately and combined for each test compound or procedure. Categorization of primary irritation potential of test compounds facilitates evaluation and reporting (Appendix).

RESULTS

The results of the individual tests comprising this study are reported to coincide with the objective of the individual test.

Objective 1: The two animals used in this pilot study showed severe burns for Decon I, Decon II and Decon I and Decon II combined. Separate and combined scores placed these compounds in category IV.

Objectives 2a through 4 are reported in Tables 4 through 12.

TABLE 4 (9)

PRIMARY DERMAL IRRITATION INDEX FOR M-258A-1 DECONTAMINATION KITS

Chemical	Intact Score	Abraded Score	Combined Score	Category
Decon I	5.7	7.5	6.7	IV
Decon II	7.8	7.4	7.6	IV
Decon I+II	5.6	5.8	5.7	IV
Control	0.0	0.0	0.0	I

Objective 2b, Occluded

TABLE 5 (10)

PRIMARY DERMAL IRRITATION INDEX FOR M-258A-1 DECONTAMINATION KITS

Chemical	Intact Score	Abraded Score	Combined Score	Category
Decon I	0.75	1.25	0.92	II
Decon II	1.83	0.67	1.25	II
Decon I+II	0.75	1.13	1.00	II
Control	0.33	0.17	0.25	I

2b, Non-Occluded

TABLE 6 (11)

PRIMARY DERMAL IRRITATION INDEX FOR M-258A-1 DECONTAMINATION KITS

Chemical	Intact Score	Abraded Score	Combined Score	Category
Decon I	1.00	3.33	2.17	II
Decon II	0.67	1.33	1.00	II
Decon I+II	4.50	3.00	3.75	III
Control	0.00	0.00	0.00	I

Objective 2c, Occluded

TABLE 7 (12)

PRIMARY DERMAL IRRITATION INDEX FOR M-258A-1 DECONTAMINATION KIT
AFTER RINSING THREE TIMES AND OCCLUDING FOR 24 HOURS

Chemical	Intact Score	Abraded Score	Combined Score	Category
Decon I	0.17	0.50	0.33	I
Decon II	0.00	0.50	0.33	I
Decon I+II	0.00	0.50	0.25	I
Control	0.00	0.00	0.00	I

2c, Non-occluded

TABLE 8 (12)

PRIMARY DERMAL IRRITATION INDEX FOR M-258A-1 DECONTAMINATION KIT
AFTER RINSING THREE TIMES AND NOT OCCLUDING

Chemical	Intact Score	Abraded Score	Combined Score	Category
Decon I	0.00	1.50	0.75	I
Decon II	0.00	0.50	0.25	I
Decon I+II	0.00	1.00	0.50	I
Control	0.00	0.17	0.08	I

Objective 3 Occluded

TABLE 9 (13)

PRIMARY DERMAL IRRITATION INDEX FOR M-258A-1 DECONTAMINATION KITS

Chemical	Intact Score	Abraded Score	Combined Score	Category
Decon I	0.5	0.83	0.67	I
Decon II	0.0	0.5	0.25	I
Decon I+II	0.33	0.08	0.25	I
Control	0.17	0.17	0.17	I

Objective 3 Non-occluded

TABLE 10 (14)

PRIMARY DERMAL IRRITATION INDEX FOR M-258A-1 DECONTAMINATION KITS

Chemical	Intact Score	Abraded Score	Combined Score	Category
Decon I	1.33	1.25	1.30	II
Decon II	1.00	0.50	0.75	II
Decon I+II	1.67	1.17	1.42	II
Control	0.17	0.17	0.17	I

Objective 4 Occluded

TABLE 11 (15)

PRIMARY DERMAL IRRITATION INDEX

ABRASIVE POTENTIAL OF THE M-258A-1 DECONTAMINATION KIT.

Treatment	Intact Score*	Abraded Score	Combined Score	Category
Wipe 1 minute	0.25	0.25	0.25	I
Wipe 3 minutes	0.33	0.83	0.58	I
Wipe 4 minutes	0.50	0.86	0.75	I
Control	0.50	0.00	0.25	I

* If intact score is less than 0.5, compounds are considered non-irritating (Category I).

Objective 4 Non-occluded

TABLE 12 (16)

PRIMARY DERMAL IRRITATION INDEX FOR THE M-258A-1 DECONTAMINATION KITS

Treatment	Intact Score*	Abraded Score	Combined Score	Category
Wipe 1 minute	0.0	0.17	0.08	I
Wipe 3 minutes	0.0	0.17	0.08	I
Wipe 4 minutes	0.0	0.0	0.0	I
Control	0.0	0.0	0.0	I

DISCUSSION

As is evidenced by the data presented in Table 4, the chemical components of the M-258A-1 Decontamination Kit present a hazard of primary dermal irritation (Category IV).

The components were re-evaluated at the concentrations that would be expected in actual usage. The results are presented in Tables 5 and 6. Even at the exposure levels expected in field use, the components still could be classified as mild irritants (Category II).

After applying the solutions of the kit (as described in the kit's instructions) and rinsing with physiological saline, no primary dermal irritation was seen (Tables 7 and 8).

The data presented in Tables 9 and 10 provide evidence that the age of the components of the kit seems to make no difference with regard to dermal irritation potential.

The data presented in Tables 11 and 12 provide evidence that the previously seen irritation was not caused by the actions of application during the testing.

CONCLUSION

The constituents of the M-258A-1 Decontamination Kit present a potential dermal irritation hazard to the user. Although the revised packaging makes it less likely that the soldier will become inadvertently exposed to the kit contents, such packaging does not modify the intentional exposure for which the kit is designed. Wiping the area of application with saline solution ameliorates the caustic activity of the kit's reagents. The impact of such rinsing on the chemical agent neutralization capability of the kit was not assessed.

RECOMMENDATIONS

Several recommendations seem warranted:

An alternative for the constituents of the kit should be sought.

A clearer determination of the effects of age on the constituents of the kit (both with regard to efficacy and toxicity) should be evaluated.

If the kit is to be continued in the system, a means of reducing the irritation (with saline rinse) should be investigated, incorporated and instruction for the use of the kit modified to include this step. The impact of such rinsing on the neutralizing capabilities of the kit needs to be evaluated.

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**Primary Skin Irritation
Categories**

APPENDIX

APPENDIX

PRIMARY SKIN IRRITATION CATEGORIES

To facilitate reporting, category symbols are used in conjunction with definitions to indicate the relative order of the skin-irritating properties of the chemical tested. The categories are as follows:

CATEGORY I - Compounds producing no primary irritation of intact skin, or no greater than mild primary irritation of the skin surrounding an abrasion.

Primary irritation score limits: (Intact 0 - 0.5)
(Abraded .51 - 2.0)
(Intact + Abraded .51 - 2.0)

The interpretation is that there is no restriction for acute application to human skin.

CATEGORY II - Compounds producing mild primary irritation of intact skin, and of the skin surrounding an abrasion.

Primary irritation score limits: 0.51 - 2.0 (Intact > 0.5)

The interpretation is that the compound should be used only on human skin found by examination to have no abrasion, or may be used as a clothing impregnant. However, if the compound might come in contact with abraded skin, a prophetic patch test should be conducted on human skin to determine primary irritation potential.

CATEGORY III - Compounds producing moderate primary irritation of intact skin and of the skin surrounding an abrasion.

Primary irritation score limits: 2.1 - 5.0

The interpretation is that the compound should not be used directly on the skin without a prophetic patch test having been conducted on humans to determine irritation potential to human skin, but may be used with patch testing with extreme caution in clothing impregnants. Compound should be resubmitted in the form and at the intended use concentration, so that its irritation potential can be reclaimed using other testing techniques on animals prior to human testing.

CATEGORY IV - Compounds producing moderate to severe primary irritation of intact skin, and of skin surrounding an abrasion. In addition these compounds produce necrosis, vesiculation, ulceration and/or eschars.

Primary irritation score limit: 5.1 - 7.9

The interpretation is that the compound should be resubmitted in the form and at the intended use concentration. The irritation potential should be reexamined using other test techniques on animals prior to prophetic patch testing in humans at concentrations, which have been shown not to produce primary irritation in animals.

CATEGORY V - Compounds which are impossible to classify because of staining of the skin or because of other masking effects owing to physical properties.

Primary irritation score limits: 8.0

The interpretation is that the compound is not suitable for use on human skin.

* Personal communication A.H. McCreesh, Army Environmental Health Agency, Aberdeen Proving Ground, MD.

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